

STUDY PROTOCOL

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The effect of psychoeducational intervention, based on a self-regulation model on menstrual distress in adolescents: a protocol of a randomized controlled trial

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Abstract

Introduction: Menstrual distress caused by primary dysmenorrhea is associated with physical and psychological symptoms—before, after, and during menstruation. Leventhal's self-regulation educational model is based on the cognitive and emotional experiences of threat responses to symptoms and relates to coping responses. This study aims to investigate the effect of the implementation of a psychoeducational intervention, based on the self-regulation model of menstrual distress in adolescents.

Methods/design: In this randomized controlled trial, 120 adolescent girls with moderate to severe menstrual pain (based on visual analog scale (VAS) ≥ 4) from twelve randomly selected high schools in Qazvin City will be enrolled in the study and will be randomly assigned to either a 3-session psychoeducational intervention ($n = 60$) or control ($n = 60$) groups. The sessions will be between 60 and 90 min apiece, and they will run for three consecutive weeks (one session per week). The data collection tools will include questionnaire eliciting menstrual information and demographics, the VAS, the Moos Menstrual Distress Questionnaire, and the illness perception questionnaire. One month prior to the intervention, both groups will participate in an initial assessment to assess the severity of their pain and level of menstrual distress. Finally, all questionnaires will be completed for three consecutive months after the intervention is completed.

Discussion: It is anticipated that findings of this study will provide evidence for the effectiveness of the Leventhal self-regulation model. Implications for improved practice, understanding, and treatment for menstrual distress may also arise.

Ethical considerations: The research protocol will be reviewed by the ethics committee, which is affiliated with the Qazvin University of Medical Sciences (Decree code: IR.QUMS.REC.1398.043).

Trial registration: [IRCT20190625044002N1](https://www.clinicaltrials.gov/ct2/show/study?term=IRCT20190625044002N1&rank=1). Registration date: 2019-09-03.

Keywords: Menstrual distress, Dysmenorrhea, Illness perceptions, Self-regulation model

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